



LETTER TO ALL RESPIRATOR MANUFACTURERS

Subject: Voluntary Program for Acceptance of Applications for the Testing and Evaluation of Air-Purifying Escape Respirators and Self-Contained Escape Respirators for Use Against Chemical, Biological, Radiological and Nuclear (CBRN) Agents

It is imperative that the general working population be afforded effective respiratory protection in escaping from terrorist events involving possible chemical, biological, radiological and nuclear (CBRN) agents. Due to ongoing concern of a potential terrorist event and the need to provide the general working population with the best available respiratory protection as quickly as possible, the National Institute for Occupational Safety and Health (NIOSH) (or the Institute) is instituting this voluntary approval program on an expedited basis. The Institute will begin accepting applications on November 6, 2003, to test and evaluate air-purifying escape respirators for use against CBRN agents. The Institute will begin accepting applications on January 2, 2004, to test and evaluate self-contained escape respirators for use against CBRN agents. This letter informs manufacturers of voluntary requirements that air-purifying escape respirators and self-contained escape respirators must meet in order to obtain NIOSH approval. It also provides the procedures for the submission of applications for these approvals.

In April 2000, NIOSH entered into a Memorandum of Understanding with the National Institute for Standards and Technology (NIST), the Occupational Safety and Health Administration, and the National Fire Protection Association (NFPA) to work on the development of standards for all types of counter-terrorism respiratory protective equipment. NIOSH and NIST initiated Interagency Agreements with the U.S. Army Soldier and Biological Chemical Command (SBCCOM) for development of respiratory protection standards, test procedures and laboratory support. The new requirements for an air-purifying escape respirator and self-contained escape respirator certification have been developed under these agreements, and are responsive to public comments NIOSH received during three public meetings, numerous stakeholder meetings and to the NIOSH docket. NIOSH initiates this voluntary approval program pursuant to Title 42, *Code of Federal Regulations* (CFR), Part 84.60(b), 84.63(c), and 84.110(c). These sections provide NIOSH with the authority to issue approvals for respirators not specifically addressed in Part 84 and to develop additional requirements that the agency determines are "necessary to establish the

quality, effectiveness and safety of any respirator used as protection against hazardous atmospheres.”

NIOSH will issue an approval and approval labels identifying the air-purifying escape respirators and self-contained escape respirators as appropriate for use against CBRN agents.

Requirements for Approval

To be approved for use in providing protection against CBRN agents, NIOSH has determined that an air-purifying escape respirator must be evaluated against the criteria defined in the Statement of Standard for Chemical, Biological, Radiological and Nuclear (CBRN) Air-Purifying Escape Respirator dated September 30, 2003. ([Attachment A](#))

To be approved for use in providing protection against CBRN agents, NIOSH has determined that a self-contained escape respirator must be evaluated against the criteria defined in the Statement of Standard for Chemical, Biological, Radiological and Nuclear (CBRN) Self-Contained Escape Respirator dated September 30, 2003. ([Attachment B](#))

Applications will be processed in the order in which they are received by the Institute. Priority of applications received on the same day will be based on a random selection from all applications received on that day. The applicant shall provide three complete respirator systems with the application. Two of the submitted units will be used for testing in accordance with Chemical Agent Penetration and permeation Resistance Against Distilled Sulfur Mustard (HD) and Sarin (GB) Agent Requirement and one will be used for general examination. The applicant will have eight weeks following notification of successful completion of the GB and HD tests, to complete the application with data from pretesting conducted by or for the applicant and remaining test equipment. See Attachment C, Guidelines for Identification of Test Configurations for Exposure to GB/HD and Part Number Change Guidelines for use in determining respirator configurations for test: Attachment D, Test Equipment and Test Data, Approval Labels and Markings contains information for providing test equipment, test data and approval labels and Attachment E, CBRN Escape Respirator Certification Costs, identifies test and evaluation fees and contains additional information about the application procedure.

Notification to Users and Regulatory Agencies

NIOSH will maintain and disseminate approval lists for respirators approved under this program. These lists will be entitled CBRN Air-Purifying Escape Respirators and CBRN Self-Contained Escape Respirators. The lists will contain the manufacturer, model, component parts, accessories, and rated duration. These lists will be maintained as a separate category within the NIOSH Certified Equipment List.

NIOSH will also disseminate the list of approved CBRN Air-Purifying Escape Respirators and CBRN Self-Contained Escape Respirators by maintaining the list on its website, www.cdc.gov/niosh/homepage.html, and seek to have it placed on or linked to other appropriate websites that disseminate information regarding respiratory protection. In addition, NIOSH will supply the list to the Occupational Safety and Health Administration for dissemination to its district offices.

Respirator Identification / Labeling

In accordance with the requirements of paragraph 84.33 of Title 42, CFR, Subpart D, approval labels for the air-purifying escape respirator shall be marked with a CBRN Rating as determined by Paragraph 4.1, Duration Rating, of the Statement of Standard for Chemical, Biological, Radiological and Nuclear Air-Purifying Escape Respirator, dated September 30, 2003.

NIOSH will authorize the use of an additional approval label on the self-contained escape respirator that demonstrates compliance to the CBRN criteria. This label is to be placed in a visible location. The addition of this label will provide visible and easy identification of equipment for its appropriate use. In accordance with the requirements of paragraph 84.33 of Title 42, CFR, Subpart D, approval labels shall be marked with a CBRN rating as determined by Paragraph 4.1, Duration Rating, of the Statement of Standard for Chemical, Biological, Radiological and Nuclear Self-Contained Escape Respirator, dated September 30, 2003.

Cautions and Limitations for both types of escape respirators, Attachment F, must be incorporated as appropriate to type, into the manufacturers' instructions for use and canister label.

Standard Test Procedures that will be used to test and evaluate both types of escape respirators will be available on the NIOSH/NPPTL web site, <http://www.cdc.gov/niosh/npptl/default.html>.

If you need additional information, please contact: NIOSH at 412-386-4000 or e-mail at npptl@cdc.gov.

Sincerely yours,

Roland J. Berry Ann
Branch Chief
Respirator Branch
National Personal Protective Technology Laboratory

Enclosures